

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Art Unit: 1654
)	
DJURUP, et al.)	Examiner: GUDIBANDE, S.
)	
Serial No.: 10/524,434)	Washington, D.C.
)	
Filed: February 15, 2005)	December 9, 2008
)	
For: BACTERICIDAL, ANTI-)	Docket No.: DJURUP=1
APOPTOTIC, PRO-)	
INFLAMMATORY AND...)	Confirmation No.: 4128

COMMUNICATION

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Sir:

We thank examiners Gudibande, Kosar and Tsang for the interview summary record faxed December 9, which "withdraws the finality of" the office action, and says that a non-final action will follow.

The Petition for Supervisory Review e-filed earlier today is mooted by the withdraw of finality, as the October 27 amendment should then be entered as a matter of right.

The notice of appeal filed September 18 constituted a timely response to the March 19, 2008 final rejection. However, if finality is withdrawn, but the March 19 action otherwise left intact, it is unclear whether how and when applicants are to respond.

The amendment of October 27 was not and did not purport to be a complete response to the final rejection, it merely sought to correct the typographical error in claim 74 to provide a clean record for appeal.

It could be inferred that the effect of the December 9 interview summary record is to vacate or reset the March 19 action, but it isn't clear which, and it would be best that its effect be more clearly stated.

Hence, we respectfully urge that the PTO explicitly either (1) vacate the March 19 action, or (2) not only withdraw

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finality, and set a new shortened statutory period for response of 3 months from the December 9 interview summary record, i.e., March 9, 2009.

In the meantime, by way of providing the examiner with a substantive analysis of the March 19 issues, we enclose copies of pp. 3 and 5-22 of the appeal brief we had been about to file today.

We note that the examiner's Interview Summary Record, together with the Petition for Supervisory Review, set forth the substance of the interviews of December 4 and 5.

Respectfully submitted,

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3. STATUS OF CLAIMS

Rejected: 1, 27-38, 53, 73*-79

Withdrawn: 40, 54, 57, 58, 80, 81

Allowed: None

Objected to: None 41-52

Cancelled: 2-26, 39, 55, 56, 59-72

Appealed: all rejected claims.

The final rejection mailed March 19, 2008 indicated that claim 73 was pending, and that the rejection of claim 73 under 35 USC 102 had been withdrawn, but did not list it as rejected under the written description requirement. Since claim 73 is drawn to

A pharmaceutical composition comprising
a peptide as defined in claim 1

and claim 1 is so rejected, we believe the examiner intended to include it in the rejection.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The claims are directed to peptides derived from the sequence of heparin binding protein or human neutrophil elastase (page 1, lines 7-8). The peptide cannot exceed 44 amino acids in length (page 3, line 7), and it must comprise a sequence motif defined by a formula having two cysteines (at positions 3 and 18) and 19 variable positions labeled as X^1 - X^{19} (page 3, line 10). X^1 and X^{19} can each be 1-5 amino acids (page 3, lines 23-24, 34-35), so the motif has a length of 21-29 amino acids.

The definitions of X^9 , X^{10} and X^{19} are of particular relevance, because of their relationship to the provisos whose written description is challenged by the PTO.

X^9 (page 3, line 30) is selected from Group 5 (Ala, Asn, Arg, Gln, Gly, His, Ile, Leu, Lys, Met, Phe, Pro, Ser, Thr, Trp, Tyr, and Val) (page 3, lines 20-21). Note that while the original definition of X^9 also referred to groups 1 and 3 (lines 16 and 18), those groups are completely embraced by group 5, and hence the unnecessary reference to groups 1 and 3 was deleted from the claim.

X^{10} (line 31) is selected from groups 2 (Arg and Lys), 3 (His, Ile, Leu, Met, Phe, Pro, Thr, Val, Trp, and Tyr) or 4 (Asn and Gln) (lines 17-19).

X^{19} (lines 34-35) is a sequence consisting of 2-5 amino acid residues, or a single amino acid residue selected from Group 5. (The unnecessary original reference to group 2 and 4, defined at lines 17 and 19, embraced by group 5, was deleted during prosecution).

Besides the limitations set forth in the definitions of X^1 - X^{19} (lines 23-35), there is the proviso, that when X^1 includes Pro, then X^{19} is Gln (page 4, line 1), and also a

requirement that at least one of five provisos, labeled (a)-(e), applies:

- (a) X19 is Arg or Ala,
- (b) X9 is Pro, Arg, or Gln,
- (c) X19 is Gln and X1 includes Pro,
- (d) X19 is 2-5 amino acid residues, or
- (e) X10 is Asn or Gln,

with X9, X10 and X19 being defined as previously discussed. The provisos (a)-(e) were introduced to distinguish the Pereira reference. These provisos have basis in the definitions of X9, X10 and X19 as discussed above, and in the specific sequences set forth in, e.g., original claims 27-40.

Claim 74 requires that at least one of provisos (aa)-(dd) applies. In claim 74 as finally rejected, the provisos are

- (aa) X19 is Arg,
- (bb) X19 is Pro,
- (cc) X19 is Gln and X1 includes Pro, or
- (dd) X19 is 2-5 amino acid residues.

An amendment to correct proviso (bb) to read X9 is Pro was filed Oct. 27 and entered Nov. 13.

These provisos were intended to be based on just the pHBP (20-44)-derived sequences. In those sequences, X1 is **KqgrP**, **Kqgrh**, **R**, or **nqgrP**; X9 is **Pro** or Ala; X10 is Arg or **Gln**; and X19 is **Arg**, Gln, or the **pentapeptide PRGQK** (boldfaced choices were departures from Pereira). Hence (aa) recites X19 is Arg; (bb) should have recited (and if the amendment is entered, will recite) X9 is Pro; (cc) X19 is Gln and (the reverse of the original proviso) X1 includes Pro; and (dd) that X19 is 2-5 amino acid residues. Note that

proviso (aa) is a subset of (a); that (bb), if corrected by the after final amendment, is a subset of (b); that (cc) is the same as (c); and that (dd) is the same as (d).

The present wording of (bb), X19 is Pro, finds basis in the general definition of X19 as being any of the 17 Group 5 residues, but is not supported by any of the specific mutant sequences set forth in the specification.

Claim 75 requires that at least one of (aa)-(cc) applies, and claims 76, 77 and 78, that, respectively, (aa), (bb) or (cc) applies. Obviously, only claim 77, requiring that (bb) applies, is affected by the present dispute as to entry of the "X9=Pro" amendment.

Claim 79 requires that X10 is Asn or Gln, which is effectively a requirement that proviso (e) applies.

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6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The sole issue is the propriety of the rejection of the claims for alleged failure to comply with the written description requirement.

7. ARGUMENT

The sole issue in this case is that of written description support for the limitation wherein at least one of the following conditions applies:

- (a) X19 is Arg or Ala,
- (b) X9 is Pro, Arg, or Gln,
- (c) X19 is Gln and X1 includes Pro,
- (d) X19 is 2-5 amino acid residues, or
- (e) X10 is Asn or Gln.

We respectfully direct the Board's attention to In re Johnson, 558 F.2d 1008, 194 USPQ 187 (CCPA 1977). In Johnson, the applicant had lost an interference. The sole count of the interference was species [1], which was one of 15 species explicitly disclosed in their 1963 application.

In the 1972 CIP, Johnson presented a claim in which the 1963 generic language was modified by a proviso which effectively excluded both species [1] and allegedly "equivalent" disclosed species [2]: "E and E' may not both include a divalent sulfene group and may not both include a divalent carbonyl group linking a divalent carbonyl group linking two aromatic nuclei".

The Examiner then contended that claim 1 was anticipated by or obvious over a Dutch patent (the foreign counterpart of the Johnson 1963 application) as the 1963 grandparent application didn't provide written description for the 1972 proviso, and thus couldn't be relied on.

After setting forth the facts of the rejection, the Johnson court quoted In re Wertheim, 541 F.2d 257, 191 USPQ 90, 97 (CCPA 1976) with approval:

Inventions are constantly made which
turn out not to be patentable, and

applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable.

In Wertheim, the CCPA held that the Swiss priority application, disclosing both the concentration range of 25-60% and the specific values of 36% and 50%, provided written description for the subrange 35-60%.

The Wertheim court explained that it was not enough for the PTO to argue "lack of literal support" as the basis for the written description rejection, as such would be inconsistent with established law - citing In re Lukach, 444 F.2d 967, 169 USPQ 795, 796 (CCPA 1971) - that the invention doesn't have to be described ipsis verbis with the claims.

After citing Wertheim, the Johnson court commented, "it is for the inventor to decide what *bounds* of protection he will seek", citing In re Saunders, 444 F.2d 599, 170 USPQ 213, 220 (CCPA 1971). Saunders was not a "written description" case, but the solicitor argued, on appeal of a prior art rejection, that the alleged distinctions related to limitations identified merely as "preferred" in the specification, and therefore could not be considered "critical" (i.e., a basis for patentability).

The Saunders court said (and this was quoted by Johnson), that to permit the identification of the claimed embodiment as "preferred" to govern its adjudication for nonobviousness would be to "let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought that he was first with the genus when he

filed".

The CCPA held that Johnson had basis for the "limited genus" claim. It declared

The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of §112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute. All that happened here is that appellants narrowed their claims to avoid having them read on a lost interference count.

Moreover, it said that the "factual context" out of which the §112 question arises is material to its disposition:

Here, as we hold on the facts of this case, the "written description" in the 1963 specification supported the claims in the absence of the limitation, and that specification, having described the whole, necessarily described the part remaining. The facts of the prosecution are properly presented and relied on, under these circumstances, to indicate

that appellants are merely excising the invention of another, to which they are not entitled, and are not creating an "artificial subgenus" or claiming "new matter".

As in Johnson, numerous species are here disclosed which belong to both the original genus and the limited genus resulting from the provisos.

Basis for these provisos rests in part in our pHBP (20-44)-derived sequences (593, 595-598 and 601-603, and the "reversed" sequence 599), our hNE (20-44)-derived sequences 604 and 605, and our EAA01962 (20-44)-derived sequence 606, which are compared in the table below:

Claim	X1	X9	X10	X19
pHBP' #'ing	(20-24)	(33)	(34)	(44)
SID #'ing	(1-5)	(14)	(15)	(25)
593	KqgrP	P	r	R
595	Kqgrh	a	r	R
596	KqgrP	a	r	R
597	Kqgrh	P	r	R
598	KqgrP	P	r	R
599	R(1)	F(10)	r(11)	PRGQK (21-25)
600	nqgrP	P	r	R
601	KqgrP	P	r	q
602	nqgrP	P	r	q
603	KqgrP	P	Q	R
Pereira	nqgrh	a	r	q
604	LrgGH	P	N	A
605	RrgGh	R	N	N
606	RSRQY	Q	r	A
Claim 1 X definitions	2-5 AA or 1AA of Grp2	Grp 5	Grp 2, 3, 4	2-5AA or 1AA of Grp 5

(Amino acids identified using the standard single letter code. Matches to Pereira are in lower case, deviations from Pereira in upper case. This alignment was previously provided on pages 8-9 of the December 17, 2007 amendment.)

Also as in Johnson, the provisos distinguish the prior art. Pereira teaches X1=nqgrh X9=a, X10=r, and X19=q (single AA) .

Johnson is not an isolated decision. In Ex parte

Dresser Industries, 224 USPQ 841, 844 (PTO Bd App. 1983), the Board stated that "the general rule is that a patentee may claim less than what he has the right to claim without showing criticality".

Johnson is also profitably compared with In re Driscoll, 562 F.2d 1245, 195 USPQ 434 (CCPA 1977) which relies upon it. The appealed claim was claim 13, which had a graphical formula, with five variables (R, R₁, R₂, R₃ and X).

Claim 13 was rejected under 35 USC 102 because the Examiner determined that the earlier filed applications (in particular, SN 782,756) didn't contain a written description of the subject matter of claim 13.

The '756 application contained the same structural formula as claim 13, but different definitions of R. The '756 definition of R was a Markush group with fourteen members, whereas R in appealed claim 13 was limited to "alkylsulfenyl (C₁-C₆)".

The Driscoll panel held that a skilled artisan would consider the '756 application as teaching fourteen distinct classes of compounds, each defined by a single member of the R group. Claim 13, it observed was limited to one of the fourteen. The court's emphasis was on the disclosure of the instantly claimed embodiment, rather than on the disclosure of the thirteen excised embodiments.

More generally, the Driscoll court quoted with approval the following observation by Judge Learned Hand.

If, when [applicants] yield any part of what they originally believed to be their due, they substitute a new "invention," only two courses will be

open to them: they must at the outset either prophetically divine what the art contains, or they must lay down a barrage of claims, starting with the widest and proceeding by the successive incorporation of more and more detail, until all combinations have been exhausted which can by any possibility succeed. The first is an impossible task; the second is a custom already more honored in the breach than in the observance, and its extension would only increase that surfeit of verbiage which has for long been the curse of patent practice, and has done much to discredit it. *It is impossible to imagine any public purpose which it could serve.*
[Emphasis added.]

Engineering Development Laboratories v.
Radio Corp. of America, 153 F.2d 523,
526-27, 68 USPQ 238, 241-242 (CA2 1946).

Daniels v. Daum, 214 USPQ 911 (PTO Bd Pat Interf. 1982) relates to an interference. Daniels moved to dissolve the interference as to counts 1 (Daum claim 15), 2 (16), 4(21), 5(19) and 6(20). Daniels argued that Daum claims 15-16 and 19-21 were directed to artificial subgenuses which were not supported by the Daum specification, and therefore Daum had no right to "make" the count.

Claim 15 covered only six compounds, of which three

were set forth in the Examples. The Board said, "We believe that the Daum generic disclosure coupled with the specific examples is sufficient to describe the subgenuses set forth in Daum's involved claims", citing, inter alia, Johnson as relevant authority.

MPEP 2173.05(i) has put a gloss upon Johnson: "If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson.... ("[the] specification, having described the whole, necessarily also described the part remaining".) See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984) The mere absence of a positive recitation is not basis for an exclusion".

While applicants believe that MPEP 2173.05(i) is construing Johnson too narrowly, that issue need not be resolved here, as the MPEP 2173.05(i) standard is satisfied. The alternative elements which are excluded by the provisos are ones which were positively recited in the specification, as will be demonstrated in more detail below.

7.1. Claims 1, 27-38, 53, 73

7.1.1. The Examiner concedes only that there is *ipsis verbis* support for the limitation "that when X1 includes Pro then X19 is Gln". We respectfully urge that this shows specific contemplation of the combination X19 is Gln and X1 includes Pro, and hence of proviso (c). Note that (c) is the converse of the existing proviso.

Proviso (c) is supported by the mutants SID 593, 601 and 602. Also note that in SID596, 598 and 600-3, X1

includes Pro.

7.1.2. With regard, individually, to provisos a, b, d and e, we respectfully submit that it is not new matter to claim a subset of explicitly described alternative elements, see Johnson, Dresser Industries, Driscoll, Daniels, and MPEP 2173.05(i), supra.

Plainly, if a claim said that a particular element A could be any of alternatives A1, A2, A3 or A4, it would not be new matter to limit the claim so A=A1. And one could logically present separate independent claims in which A=A2, A=A3 and A=A4, respectively.

Likewise, the applicant could choose to so claim, e.g., A=A1 and A=A2 but not A=A3 and A=A4.

That established, there is no change in the collective scope of the claims if the applicant were to claim A=A1 or A=A2 in a single claim rather than in two separate independent claims, and thus a claim to a subset of two or more disclosed alternatives does not violate the written description requirement.

Indeed, MPEP 2173.05(i) takes this principle a step further. If applicant disclose a genus, and more than one species belonging to that genus, they have written description for the explicit exclusion, from the claimed genus, of any of the positively recited alternative species. If an exclusion of any positively recited species is proper, than surely it is proper to simply claim just the desired alternatives in positive form.

7.1.3. Let us first consider proviso "a" (X19 is Arg or Ala). The original definition of X19 was "X19 can be represented by a sequence consisting of 2-5 amino acid

residues or a single amino acid residue selected from Groups 5, 2 or 4". Group 5 is defined as being one of 17 amino acids, and includes both Arg and Ala. We amended X19 to eliminate the superfluous references to groups 2 and 4, which are actually subsets of group 5.

There is specific disclosure of both X19=Arg (R) and X19=Ala (A). X19=R is supported by the pHBP (20-44) mutants which feature the mutation Q44R, e.g., SID 593, 595 (the originally elected species), 596, 597, 598, 600. X19=A is supported by SID 604 and 606.

7.1.4. Proviso (b) requires X9=Pro, Arg, or Gln. The original claim allowed X9 to be any group 5 residue.

However, all three X9 alternatives are specifically disclosed. X9=P is supported by the pHBP (20-44) mutants with A33P, i.e., 593, 597, 598 and 600-3; the HNE-based sequence SID 604 also satisfies X9=P. X9=R is supported by hHNE (20-44) derived sequence SID 605. X9=Q is supported by the EAA01962 (20-44) derived sequence SID 606.

7.1.5. Proviso (d) requires that X19 is 2-5 aa, and as we stated in the discussion of proviso (a), this was one of the alternatives explicitly recited for X19 in original claim 1.

7.1.6. Finally, proviso (e) requires that X10 is Asn (N) or Gln (Q). X10 was originally required to be an amino acid of groups 2 (Arg, Lys), 3 (His, Ile, Leu, Met, Phe, Pro, Thr, Val, Trp, or Tyr) or 4 (Asn, Gln), i.e., one of 14 amino acids. We first point out that since the proviso (e) choices are from, and only from, group 4, that proviso (e) effectively limits X10 to the defined amino acid group 4, for which subset of AAs there is thus explicit recognition. X19 being Asn is supported by SID604 and 605, and being Gln

by SID603.

7.1.7. It follows from the foregoing that we have written description for five independent claims, the first reciting proviso (a); the second, proviso (b); and so forth. Consequently, it cannot be violation of written description to combine these five hypothetical independent claims into a single claim, like the present claim, whose scope is no greater than what those five hypothetical claims would have, collectively.

7.2. Claim 79

Claim 79 effectively makes mandatory the requirements of proviso (e), i.e., that X10 is Asn or Gln. Since proviso (e) is satisfied, provisos (a)-(d) can be ignored, and written description for claim 79 turns solely on the issue of written description for proviso (e). We have already explained above, in section 7.1.6, why such written description exists.

7.3. Claim 74

Claims 74 requires that at least one of provisos (aa)-(dd) apply.

X19=Arg (R), per proviso (aa), is supported by the pHBP (20-44) mutants which feature the mutation Q 44R, e.g., SID 593, 595 (the originally elected species), 596, 597, 598, 600. X19=A is supported by SID 604 and 606.

X19=Pro, per the proviso (bb) as finally rejected, is supported by the definition of X19 as being a group 5 residue, which is defined to include Pro.

If the questioned amendment is entered, proviso (bb)

instead requires X9=Pro (P), which is supported by the pHPB (20-44) mutants with A33P, i.e., 593, 597, 598 and 600-3; the HNE-based sequence SID 604 also satisfies X9=P.

X19=Gln (Q) and X1 includes proline, per proviso (cc), is supported by the mutants SID 593, 601 and 602. Note that (c) is the converse of the existing proviso that "when X1 includes Pro, then X19 is Gln". Also note that in SID596, 598 and 600-3, X1 includes Pro.

X19 being 2-5 Aas, per proviso (dd), is one of the alternatives specified in original claim 1, and is exemplified by SID 599.

Finally, X10 being Asn is supported by SID 604 and 605, and being Gln by SID 603.

7.4. Claim 75

Claim 75 requires that at least one of provisos (aa)-(cc) applies. Hence, it is only necessary that there be written description for these provisos, as argued in section 7.3; proviso (d) of claim 74 may be ignored. We have already explained above, in section 7.3, why such written description exists.

7.5. Claim 76

Claim 76 requires only that proviso (aa) applies. Hence it is only necessary that there be written description for (aa), and all other provisos can be ignored. We have already explained above, in section 7.3, why such written description exists.

7.6. Claim 77

Claim 77 requires only that proviso (bb) applies. Hence

it is only necessary that there be written description for (bb), and all other provisos can be ignored. We have already explained above, in section 7.3, why such written description exists.

7.7. Claim 78

Claim 78 requires only that proviso (cc) applies. Hence it is only necessary that there be written description for (cc), and all other provisos can be ignored. We have already explained above, in section 7.3, why such written description exists.

8. CONCLUSION

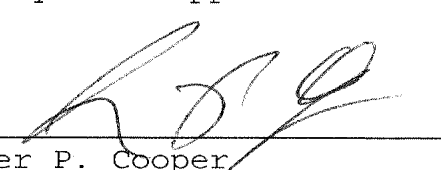
In view of the foregoing, it is respectfully urged that the rejection be reversed as to all rejected claims and the case returned to the examiner for proceedings consistent with such reversal. If the rejection of claims 1, 27-38, 53, 73 is affirmed, the Board should nonetheless separately consider the rejections of claims 74-79, each of which has been separately argued.

The appeal brief fee is enclosed. Please charge any deficiency in the fee to Deposit Account 02-4035.

Respectfully submitted,

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